

**REMARKS**

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

**Status**

Applicants' Request for Continued Examination ("RCE") filed November 21, 2003, has been accepted and the corresponding submission has been entered. Accordingly, as is correctly indicated in the Office Action Summary, Claims 29-31, 33-36, and 38-55 are pending. Claims 29-31, 33-36, and 38-53 stand rejected. Claims 54 and 55 are objected to.

Acknowledgment has been made to a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f) and all certified copies of the priority documents have been received.

**Summary of Amendments**

By the foregoing amendments, Claim 51 was amended to read "wherein a whole plant is cultured," as recommended by the Examiner. *See Official Action mailed February 17, 2004, Pages 2-3, ¶ 4.* Support for this amendment may be found at least in the previously-presented claim and no new matter has been added.

Also by the foregoing amendments, Claim 54 was amended to delete the purportedly improper multiple-dependent phrase "the nucleotide sequence of Claim 29" and to add the content of said phrase. *See Official Action mailed February 17,*

2004, Page 3, ¶ 5. Support for this amendment may be found at least at previously presented Claims 29 and 54 and no new matter has been added.

Further by the foregoing amendments, Claim 55 was amended to delete the purportedly improper multiple-dependent phrase "the nucleotide sequence of Claim 34" and to add the content of said phrase. *See Official Action mailed February 17, 2004, Page 3, ¶ 5.* Support for this amendment may be found at least at previously presented Claims 34 and 55 and no new matter has been added.

Further by the foregoing amendments, Claims 29 and 34 were amended to correct a minor and typographical error in the article preceding "N-methyl transferase" in line two of these claims. *See Official Action mailed February 17, 2004, Page 3, ¶ 6.* Support for these amendments may be found at previously-presented Claims 29 and 34 and no new matter has been added.

Further by the foregoing amendments, Claim 30 was amended to delete the purportedly improper multiple-dependent phrase "the nucleotide sequence of Claim 29" and to add the content of said phrase. *See Official Action mailed February 17, 2003, Pages 9-10, ¶ 9.* Support for this amendment may be found at least at previously-presented Claim 30 and no new matter has been added.

Finally by the foregoing amendments, Claim 35 was amended to delete the purportedly improper multiple-dependent phrase "the nucleotide sequence of Claim 34" and to add the content of said phrase. *See Official Action mailed February 17, 2003, Pages 9-10, ¶ 9.* Support for this amendment may be found at least at previously-presented Claim 35 and no new matter has been added.

### **Personal Interview**

Applicants and the undersigned wish to thank Examiner Kubelik for the courtesies extended during the Personal Interview ("Interview") conducted for this case on March 12, 2004. During the Interview, the pending claims, the pending 35 U.S.C. § 112 rejections, and possible claim amendments were discussed, as indicated by the Interview Summary sheet.

### **Rejections Under 35 U.S.C. § 112, First Paragraph – Enablement**

Claims 29-31, 34-36, and 39-53 stand rejected under 35 U.S.C. § 112, First Paragraph, as purportedly not enabled. *See Official Action mailed February 17, 2004, Pages 3-8.* According to the Examiner, the instant application "does not reasonably provide enablement for nucleic acids that encode SEQ ID NO:1 or nucleic acids that have 90% identity to any nucleic acid that encodes SEQ ID NO:1 or for RNA vectors and plants transformed therewith." *Id.* at 3. This rejection is respectfully traversed.

"The test of enablement is not whether **any** experimentation is necessary, but whether, if experimentation is necessary, it is **undue**." *See M.P.E.P. § 2164.01* (emphasis added). Applicants maintain that one of skill in the art can readily both make and use Applicants' invention, as described in Claims 29-31, 34-36, and 39-53, without **undue** experimentation.

Applicants submit that one of ordinary skill in the art can readily make and determine the activity of an isolated DNA/RNA molecule comprising a nucleotide sequence encoding the N-methyl transferase of SEQ ID NO:1, as the 356 amino acids of SEQ ID NO:1 are explicitly set forth in the instant application. *See Claims*

29, 34. Similarly, one of ordinary skill in the art can readily make and determine the activity of an isolated DNA molecule consisting of SEQ ID NO:2, as SEQ ID NO:2 is also explicitly set forth in the instant application. *See Claims 33, 38.* Applicants further submit that one of ordinary skill in the art can readily make a vector comprising such DNA/RNA molecules. *See Claims 41, 52.* As such, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, First Paragraph, enablement rejection against at least Claims 29, 33, 34, 38, 41, and 52.

Turning now to the claims having at least 90% identity to the identified nucleotide sequences, Applicants similarly maintain that it is well within the purview of the skilled artisan to produce modified sequences and then to determine whether such modified sequences maintain the desired enzymatic activity. *See Claims 30, 31, 35, 36, 53, 54, 55.* While creation and screening of said sequences may, in fact, require experimentation, such experimentation is by no means undue and has become quite routine in the art. As such, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, First Paragraph, enablement rejection against at least Claims 30, 31, 35, 36, 53, 54, and 55.

Regarding the remaining claims, the Examiner asserts that "[t]here is no evidence to suggest that a nucleic acid encoding only SEQ ID NO:1 would function to encode an enzyme with the listed properties, especially since the starting methionine is missing." *See Official Action mailed February 17, 2004, Page 6.* Applicants respectfully disagree.

The amino acid sequence set forth in SEQ ID NO:1 is thirteen (13) amino acids shorter in length than the amino acid set forth by Kato *et al.* in 406 NATURE 956-957 (2000). The amino acid of SEQ ID NO:1 was obtained from the enzyme

separated and isolated from tea leaves, as described in Example 1. In Example 2, the N-terminus amino acid sequence was confirmed and the single cDNA strand was synthesized based on the corresponding RNA using polymerase chain reaction ("PCR"), as set forth in Example 4. The amino acid sequence of SEQ ID NO:1 was determined in Example 9 (which pertains to Examples 5 and 8).

The nucleotide sequence of SEQ ID NO: 2 was obtained through analysis of the cDNA, including the excess portion. As the N-terminus amino acid sequence had already been determined in Example 2, SEQ ID NO: 2 afforded determination of the remainder of SEQ ID NO: 1.

The sequence beginning with "ttc atg aac" (the first "t" being at position 99 of SEQ ID NO:2) corresponds to the beginning sequence of "Phe Met Asn" of SEQ ID NO:1. The sequence that begins "atg gag cta" (the first "a" being at position 60 of SEQ ID NO:2) encodes the 369 amino acid enzyme set forth in Kato. The enzyme of SEQ ID NO:1 is a shortened fragment of the Kato enzyme that possesses enzyme activity.

The examples set forth in the instant application demonstrate that the enzyme of SEQ ID NO:1 is enabled. As discussed above, the short enzyme of SEQ ID NO:1 was obtained tea leaves, SEQ ID NO:1 indicating the amino acid sequence of the mature protein.

Contrarily, in Kato cDNA was first synthesized based on mRNA and cDNA was cloned into an *E. coli* host to express the long enzyme. Kato simply determined the nucleotide sequence of the long enzyme based on the cDNA, as Kato did not evaluate the N-terminus amino acid sequence [obtained in instant Example 2]. As

such, Kato's sequence is the gene encoding the enzyme yet containing the structural gene, exons, and introns – the same form as it had in the *E. coli* host.

In the cells of tea leaves, the precursor is cleaved to form the mature enzyme, the enzyme evidenced by SEQ ID NO:1. As such, the first amino acid of SEQ ID NO: 1 is not "Met," but "Phe" – this being caused by the processing from precursor to mature enzyme Example 2 clearly established that the enzyme acting in cells of the tea leaves has "Phe" at the first amino acid of the N-terminus.

Based on the foregoing, it is evident that the instant application allows one of skill in the art to both make and use SEQ ID NO:1. By extension, Applicants' claims relying upon the use of SEQ ID NO:1, such as Claims 39, 40, and 42-51, may also be made and used. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, First Paragraph, enablement rejection against remaining Claims 39, 40, and 42-51 be withdrawn.

#### **Rejections Under 35 U.S.C. § 112, First Paragraph – Written Description**

Claims 29-31, 34-36, and 39-53 stand rejected under 35 U.S.C. § 112, First Paragraph, as purportedly lacking sufficient written description. *See Official Action mailed February 17, 2004, Pages 8-9, ¶ 8.* This rejection is respectfully traversed.

As explained in detail above with respect to the enablement rejection, Applicants maintain that those of ordinary skill in the art would readily agree that Applicants are in possession of the subject matter described in Claims 29-31, 34-36, and 39-53.

**Rejections Under 35 U.S.C. § 112, Second Paragraph – Indefiniteness**

Claims 30-31, 35-36, 40, 42, 44, 46, 48-49, 51, and 53 stand rejected under 35 U.S.C. § 112, Second Paragraph, as purportedly indefinite. *See Official Action mailed February 17, 2004, Pages 9-11, ¶ 9.* This rejection is respectfully traversed.

Not to acquiesce in the Examiner's rejections, but solely to facilitate prosecution, Applicants have amended Claims 30 and 35 so as to delete the purportedly improper multiple-dependent phrase "the nucleotide sequence of claim" 29 and 34, respectively. Applicants have further amended Claims 30 and 35 to add the content of the deleted phrases. Applicants believe the foregoing amendments have rendered moot the 35 U.S.C. § 112, Second Paragraph, rejection of Claims 30 and 35. Accordingly, Applicants respectfully request withdrawal of said rejections.

Claim 49 was rejected under 35 U.S.C. § 112, Second Paragraph, as purportedly indefinite due to the phrase "said transformed plant cell, plant tissue, or whole plant" in lines 4 and 3, respectively. *See Official Action mailed February 17, 2004, Page 10, ¶ 9.* Applicants respectfully request clarification as to this rejection, as the cited phrase does not appear in pending Claim 49.

Claims 49 and 50 were rejected under 35 U.S.C. § 112, Second Paragraph, as purportedly indefinite due to the phrase "plant body." According to the Examiner, "[c]ulturing a whole plant to form a plant body would therefor mean culturing a whole plant to form a whole individual plant; the phrase is redundant and meaningless." *See Official Action mailed February 17, 2004, Page 11, ¶ 9.* Applicants respectfully traverse this rejection. As noted by the Examiner, the Specification defines, in Paragraph 0063, the term "plant body" as meaning the whole individual organism classified into plant or organ parts thereof, such as leaves, stems, roots, . . . ."

Because the definition allows for organ parts thereof, and not simply the whole individual organism, Applicants respectfully submit that the phrase "plant body" is neither redundant nor meaningless. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, Second Paragraph, rejection against Claims 49 and 50.



**CONCLUSION**


From the foregoing, further and favorable consideration in the form of a Notice of Allowance is respectfully requested and earnestly solicited.

In the event that there are any questions relating to this Amendment and Reply, or the application in general, it would be greatly appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,  
BURNS, DOANE, SWECKER & MATHIS, L.L.P.

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By: \_\_\_\_\_

  
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